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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,676	09/22/2003	Garth Boehm	224562	9396

23460	7590	08/02/2007
LEYDIG VOIT & MAYER, LTD		
TWO PRUDENTIAL PLAZA, SUITE 4900		
180 NORTH STETSON AVENUE		
CHICAGO, IL 60601-6731		

EXAMINER
AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
08/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,676	Applicant(s) BOEHM, GARTH	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-36 and 38 is/are rejected.
- 7) ☒ Claim(s) 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12222003 & 01292004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the information disclosure statements filed 12/22/2003 and 01/29/2004.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 04/23/2007 is acknowledged. The traversal is on the ground(s) that there is no serious burden in searching both groups I and II, and further, that the species of Group II do not pose an undue burden on this office. After review of the claims, applicant's arguments are persuasive. Groups I and II will be examined in their entirety. Group II however will be considered non-elected.

The requirement is still deemed proper and is therefore made FINAL.

Claim 37 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/23/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 20-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Breder et al (US 2003/0157168)

Breder et al disclose an oral dosage form which comprises a sequestered opioid antagonist which is substantially not released when intact (see Abstract). Hydrophobic materials are disclosed for use in coating and sequestering the antagonists (see page 10, [0123]). In particular, cellulose polymers and acrylic polymers are set out at [0123] –[0127]. Other hydrophobic polymers suitable to coat the antagonist are listed at [0128]. Ph dependent or enteric coatings are disclosed at [0145] –[0157]. These include Eudragit polymers which have an ammonium content. Figure 2 shows that the applied coating substantially prevents release of the antagonist for up to 36 hrs. The reference discloses the same hydrophobic barrier polymers disclosed for the same art recognized purpose of sequestering antagonists, therefore the coating of the reference would inherently prevent release for the same 72 hrs as claimed herein, and is capable of preventing the same amount of that substance to be released. Capsules and tablets are set out as preferred embodiments at [0135]. Opioid agonists are listed at [0099 – 0101]. Opioid antagonists are listed at [0108 – 0110]. Beads coated with an opioid agonist , and opioid antagonist in non-releasable form are disclosed at [0164] and entail multiple subunits with releasable therapeutic with a coated (sequestered) antagonist in each.

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Subunits with either agonist or antagonist are set out at [0213]. A Hydrophilic core, with an aversive agent coating further coated with a hydrophobic agent is listed at [0166] – [0167]. The instant claims are anticipated by Breder et al.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 20-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Breder et al.

Breder et al disclose an oral dosage form which comprises a sequestered opioid antagonist which is substantially not released when intact (see Abstract). Hydrophobic materials are disclosed for use in coating and sequestering the antagonists (see page 10, [0123]). In particular, cellulose polymers and acrylic polymers are set out at [0123] – [0127]. Other hydrophobic polymers suitable to coat the antagonist are listed at [0128]. Ph. dependent or enteric coatings are disclosed at [0145] – [0157]. These include Eudragit polymers which have an ammonium content. Figure 2 shows that the applied coating substantially prevents release of the antagonist for up to 36 hrs. The reference discloses the same hydrophobic barrier polymers disclosed for the same art recognized purpose of sequestering antagonists, therefore the coating of the reference would inherently prevent release for the same 72 hrs as claimed herein, and is capable of preventing the same amount of that substance to be released. Capsules and tablets are set out as preferred embodiments at [0135]. Opioid agonists are listed at [0099 – 0101]. Opioid antagonists are listed at [0108 – 0110]. Beads coated with an opioid agonist, and opioid antagonist in non-releasable form are disclosed at [0164] and entail multiple

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subunits with releasable therapeutic with a coated (sequestered) antagonist in each.

Subunits with either agonist or antagonist are set out at [0213]. A Hydrophilic core, with an aversive agent coating further coated with a hydrophobic agent is listed at [0166] – [0167]. The instant claims are anticipated by Breder et al.

Claims 1-14, 18-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al (US 2003/0064099).

Oshlack et al disclose an oral dosage form which comprises a sequestered opioid irritants and bittering agents which are substantially not released when intact (see Abstract). Hydrophobic materials are disclosed for use in coating and sequestering the antagonists. In particular, cellulose polymers and acrylic polymers are set out at [0605] – [0075]. Ph dependent or enteric coatings are disclosed at [0139] – [0141]. These include Eudragit polymers which have an ammonium content. The reference discloses the same hydrophobic barrier polymers disclosed for the same art recognized purpose of sequestering antagonists, therefore the coating of the reference would inherently prevent release for the same 72 hrs as claimed herein, and is capable of preventing the same amount of that substance to be released. Capsules and tablets are set out as preferred embodiments at [0077] - [0082]. Opioid agonists are listed at [0056 – 0063]. The aversive agents (irritants and bittering agents) are listed at [0044 –

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[0055]. Beads coated with an opioid agonist , and opioid antagonist in non-releasable form are disclosed at [0084] and entail multiple subunits with releasable therapeutic with a coated (sequestered) antagonist in each. Subunits with either agonist or antagonist are set out at this paragraph. A Hydrophilic core, with an aversive agent coating further coated with a hydrophobic agent is listed at [0086]. The instant claims are anticipated by Oshlack et al.

Claims 1-14, 18-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshlack et al . (US 2003/0064099).

Oshlack et al disclose an oral dosage form which comprises a sequestered opioid irritants and bittering agents which are substantially not released when intact (see Abstract). Hydrophobic materials are disclosed for use in coating and sequestering the antagonists. In particular, cellulose polymers and acrylic polymers are set out at [0605] –[0075]. Ph dependent or enteric coatings are disclosed at [0139] –[0141]. These include Eudragit polymers which have an ammonium content. The reference discloses the same hydrophobic barrier polymers disclosed for the same art recognized purpose of sequestering antagonists, therefore the coating of the reference would inherently prevent release for the same 72 hrs as claimed herein, and is capable of preventing the same amount of that substance to be released. Capsules and tablets are set out as preferred embodiments at [0077] –[0082]. Opioid agonists are listed at [0056 – 0063]. The aversive agents (irritants and bittering agents) are listed at [0044 –

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-17 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breder et al.

Breder et al disclose sequestering various aversive agents behind coatings of hydrophobic materials (see discussion of the disclosure above). While the specific coating pattern of the instant claims is not specifically disclosed by Breder et al, Breder et al does suggest multiple coating formulations with respect to the discussion of the

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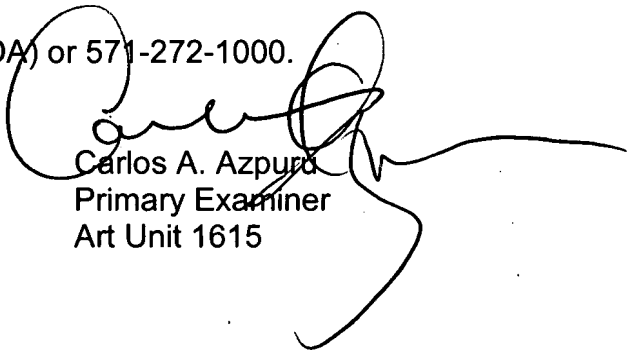
figures. As such, those of ordinary skill at the time of invention would have found it well within their skill to apply any number of hydrophobic coatings and aversive agent layers including those of the instant claims with a reasonable expectation of discouraging opioid abuse. As such, the instant claims would have been obvious to one of ordinary skill in the pharmaceutical arts at the time of invention given the disclosure of Breder et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpur
Primary Examiner
Art Unit 1615

caz